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10/557,515	11/21/2005	Mashihiro Fukuzawa	10921.367USWO	8816
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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			MCEVOY, THOMAS M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,515	Applicant(s) FUKUZAWA ET AL.	
	Examiner THOMAS MCEVOY	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 24, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/1/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1st 2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner does not see where an elastic member at the end of a groove of the first or second moving member impacts the second moving member during the retreating movement of the second moving member.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is structurally claimed since it appears that there is no elastic member at the end of a groove of the first or second moving member which impacts the second moving member during the retreating movement of the second moving member.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schraga (US 2003/0050656).

Regarding claims 1 and 27, Schraga discloses a lancing device comprising: a first moving member 24 holding a lancing member 25 moved from a standby position (Figure 2) to a puncturing position (Figure 5; or any position distal of the standby position) in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 40 connected to the first moving member for controlling the

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movement of the first moving member; a housing 20 for accommodating the first and the second moving members while allowing the movement of the moving members; a movement converting mechanism (interaction of 28, 30 and 44) for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position (the second moving member could be moved to a distal point just before member 47 is latched and then moved proximally to cause advancing movement of the first moving member); and an impact absorbing means that comes into stopping contact with the second moving member in the retreating movement for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation (member 46/47 must come into stopping contact with the housing wall or member 40 must come into stopping contact with the opening of the housing; Applicant's disclosure makes clear that the scope of an impact absorbing means can include portions of already claimed members like the tapered opening of the second moving member). Regarding claim 28, in the Figure 8 embodiment the second moving member 60 is latched to the housing (at 65) at the advanced position while being urged toward the retreated position (otherwise member 65 would not be needed); wherein when the second moving member is unlatched from the housing, the second moving member moves from the advanced position toward the retreated position for causing the lancing member to move toward the puncturing position together with the first moving member (the second moving member could be moved to a distal point just before member 64 is latched and then moved proximally to cause advancing movement of the first moving member).

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8. Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent).

Regarding claims 1 and 27, Garthe et al. disclose a lancing device comprising: a first moving member, 40 or 51 or 40/51, holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 60 or 60/61 connected to the first moving member, for controlling the movement of the first moving member; a housing 11 for accommodating the first and the second moving members, while allowing the movement of the moving members; a movement converting mechanism 61/52/53 (a mechanism can comprise already claimed structural components; Examiner notes that Applicant's mechanism requires the grooves of the first and second moving members to function) for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position; and an impact absorbing means 53', connected to the housing, that comes into stopping contact with the second moving member in the retreating movement for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation.

9. Claims 1-4, 6, 7, 9, 24 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitson et al. (US 7,144,404 B2).

Regarding claims 1-3, 6 and 27, Whitson et al. disclose a lancing device comprising: a first moving member 22/24 holding a lancing member moved from a standby position (position 4, Figure 7) to a puncturing position (position 1, Figure 7; a

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position ready to initiate puncturing, etc.; the claim term is not well defined) in a puncturing direction (in moving from 4 to 1, the first moving member moves in a direction towards a final puncturing position) for puncturing a target portion by the lancing member; a second moving member 12 connected to the first moving member, for controlling the movement of the first moving member; a housing 240/242 for accommodating the first and the second moving members while allowing the movement of the moving members; a movement convening mechanism for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position (evident from Figures 6 and 7; note horizontal line of cross-hairs in Figure 7 demarking a longitudinal position of the first moving member; note that second moving member is retreating from positions 3 to 4 to 1); and an elastically deforming impact absorbing means 28 that comes into stopping contact with the second moving member in the retreating movement (spring 28 is biased in puncturing direction so it must provide resistance to stop or assist in stopping member 12; Examiner notes that this recoil portion of the retreating movement in this application and the prior art does not result in opposite movement of the first moving member), connected to the housing (via member 90) for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation. Regarding claim 4, the housing is provided with a projection 90 for fixing the elastic member, the elastic member being a ring (series of rings) fitting around the projection. Regarding claim 7, member 90 can be considered as an operating portion and it connects to members 288/289 through an open end of the

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housing. Regarding claim 9, the movement converting mechanism comprises a link 16 connecting the first and second moving members and the second moving member 12 has grooves which allow the shaft of the link to rotate and therefore move. Regarding claim 24, reciprocal (up and down) movement of the second moving member (positions 1 to 2 to 3 to 4 to 1, Figure 7) is transformed into reciprocal movement of the first moving member (see comments for claim 1).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2, 3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent) in view of Alden et al. (US 7,033,371 B2) and Stanton (US 2,993,698).

Regarding claims 2 and 3, Garthe et al. fail to disclose an elastically deforming impact absorbing means as claimed. Alden et al. teach that mechanical stops in a lancet (such as the groove of Garthe et al.) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Stanton discloses that a vibration transferred to a link in a groove (similar to the link and groove of Garthe et al.) can be minimized by lining the groove with rubber (col. 3, lines 1-11 and elsewhere). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (groove sections) of the Garthe et al. device as taught by Alden

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et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the groove to dampen the vibrations as taught by Stanton. Regarding claim 9, the movement converting mechanism comprises a link 61 connecting the first and the second moving members for moving the first moving member upon the movement of the second moving member, wherein the first moving member is formed with a groove for allowing movement of a shaft of the link (Figures 4A-C). Regarding claim 10, the elastic member would be provided at upper and lower ends of the groove.

12. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitson et al. (US 7,144,404 B2) in view of Alden et al. (US 7,033,371 B2) and Tone (US 4,328,879).

Regarding claims 5 and 10, Whitson et al. disclose the device as described above but fail to disclose an elastic support in the groove. Alden et al. teach that mechanical stops in a lancet (such as the grooves of member 12 of Whitson et al.; especially at the impact points 1-4) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Tone teaches that it is known in a variety of arts to line a variety of gear drives with rubber in order to minimize shock and vibration (col. 1, lines 14-29). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (grooves and corners of member 12) of the Whitson et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the parallelogram of member 12 or around gear 16 to dampen the vibrations as taught by Tone.

Response to Arguments

13. Applicant's arguments filed February 1st 2010 have been fully considered but they are not persuasive. Applicant has argued that claim 10 is enabled and has pointed out several passages and figures from the specification. Examiner respectfully disagrees. It does not seem clear how pin 30a would move into the straight portion 30Ab so that it could contact the impact absorbing means. Figures 6A-D are the key disclosure for enabling Applicant's invention and it appears that the mechanism only allows for pin 30a to move to just the end of sloped portion 30Aa and not into portion 30Ab. Figures 6A-D seem to show that this movement would be impossible. Applicant has argued that the first moving member of Garthe et al. would be advanced without the second moving member and therefore the second moving member does not move the first moving member. The second moving member provides a high mass inertia which would add to the rotational force of member 51. Regardless, the mechanism of grooves and pins is capable of converting retraction of the second moving member (caused by any means) into advancing movement of the first moving member. Applicant has argued that Whitson et al. disclose advancing movement of the second moving member during advancing movement of the first moving member to the puncturing position as shown in positions 1 and 2. Examiner has explained above how movement from positions 4 to 1 meets the claim limitations in question.

Allowable Subject Matter

14. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/11/10